Brown, Tyler

From:	Brown, Tyler
Sent:	Wednesday, October 28, 2015 11:24 AM
To:	William Broscious; Joseph McConnell; jyoung@oaktreecapital.com; Hayes, Dion W.; Lahn, Connie; Kim Taylor
Cc:	Harbour, Jason; Arrowsmith, Rick (rarrowsmith@alvarezandmarsal.com)
Subject:	CONFIDENTIAL - LR Letter
Attachments:	LR Letter-c.pdf

As requested by the Board during the meeting yesterday, attached is copy of the demand letter that Rick Arrowsmith sent to LeClair Ryan. Please treat this as confidential Board material since part of the pitch to LR will be that they should resolve this before the matter becomes public.

-Tyler

HUNTON& WILLIAMS

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HealthDiagnosticLaboratoryInc.
beyond disease diagnosis

CONFIDENTIAL COMMUNICATION
FOR SETTLEMENT PURPOSES ONLY

VIA FEDEX

Ref:
Dep:
Date: 27Oct15
Wgt: 0.50 LBS
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SVCs: PRIORITY OVERNIGHT
TRCK#: 6537 9441 4504
SHIPPING: 11.60
SPECIAL: 0.12
HANDLING: 0.00
TOTAL: 11.72

October 26, 2015

Bruce Matson
Chief Legal Officer
LeClairRyan, P.C.
919 East Main Street
24th Floor
Richmond, VA 23219

RE: Health Diagnostic Laboratory, Inc.

Dear Mr. Matson:

I am writing to you in my capacity as the estate representative for Health Diagnostic Laboratory, Inc., Central Medical Laboratory, LLC and Integrated Health Leaders, LLC (collectively, "HDL") in its capacity as debtor in possession in its chapter 11 case, Case No. 15-32919 (KRH) commenced on June 7, 2015, pending in the United States Bankruptcy Court for the Eastern District of Virginia.

You may be aware that HDL entered into a civil Settlement Agreement with the United States Department of Justice ("DOJ") on behalf of several participating federal and state agencies ("DOJ Settlement"), effective as of May 31, 2015. As part of this DOJ Settlement, HDL agreed to pay a civil penalty of $47 million[1] and entered into a five year corporate integrity agreement ("CIA") with the U.S. Department of Health and Human Services Office of Inspector General ("OIG"). The DOJ Settlement resolved allegations that HDL "knowingly submitted false or fraudulent claims to Government Healthcare Programs" and "conspiring to submit false or fraudulent claims to Government Healthcare Programs" in violation of the Federal False Claims Act[2] ("FCA"). The DOJ alleged that, during the period of November 25, 2008 through January 31, 2015, HDL:

1. "offer[ed] and/or pa[id] illegal remuneration to health care providers through 'process and handling' payments related to the collection of blood; speaker programs; advisory boards; consulting arrangements; goods and services; and gifts" in violation of the Federal Anti-Kickback Statute[3] ("AKS") and/or Stark Law;[4]

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1 The settlement amount could rise to as high as $100 million, based on certain triggering events included in the settlement agreement.
2 31 U.S.C. §§ 3729 *et seq.*
3 42 U.S.C. §1320a-7b(b).
4 42 U.S.C. §1395nn.

2. "routinely offer[ed] to waive and/or waiv[ed] cost-sharing obligations, such as copayments and deductibles, to certain TRICARE beneficiaries" in violation of the AKS;[5]

3. "submitt[ed] or caus[ed] to be submitted claims for payment to the Government Healthcare Programs for tests that were not medically necessary or that were not appropriately coded"; and

4. "offer[ed] and/or pa[id] illegal remuneration in the form of commission payments to BlueWave Healthcare Consultants, Inc." pursuant to a Sales Agreement in violation of the AKS.

Significantly, HDL repeatedly sought legal counsel and opinions from several LeClairRyan partners and attorneys between at least October 2009 and July 2012 regarding the legality of "process and handling" ("P&H") payments provided to health care providers ("HCPs") for blood collection services. Additionally, LeClairRyan provided legal counseling to HDL regarding several other problematic areas identified by the DOJ, including the BlueWave agreement and HDL's billing practices.

LeClairRyan's responses to HDL for its requests for legal counsel relating to the legality of P&H payments during this time period were negligent. This negligence resulted in significant costs to HDL including, at a minimum, increased penalties in the DOJ Settlement. Corporate assets were compromised as a result of the DOJ Settlement. HDL is now seeking an equitable amount from LeClairRyan for damages that it suffered due to LeClairRyan's negligence.

Factual Background

As described below, LeClairRyan consistently advised HDL during the relevant time period that its P&H payments to HCPs for blood collection services were consistent with law, including the AKS and AKS Personal Services and Management Contracts safe harbor[6] ("AKS Personal Services Safe Harbor"). Specifically, LeClairRyan reviewed and approved P&H agreements and P&H position papers provided by HDL; developed legal memoranda and issued a legal letter that concluded that P&H payments were legal; and continued to advise HDL regarding the legality of P&H payments despite numerous inquiries and complaints from HCPs, competitors of HDL, and other third parties. A timeline of select key facts related to P&H payments is provided in **Attachment A**.

I. **P&H Agreements**

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5 Upon learning of the DOJ Investigation, Cigna Health and Life Insurance Company filed suit in the United States District Court for the District of Connecticut (Case No. 3:14-cv-01519-VAB) and Aetna filed suit in the United States District Court for the Eastern District of Pennsylvania (Case No. 2:15-cv-01868-RK) related to HDL's business practices (collectively, the "Civil Litigation"). The Civil Litigation seeks damages of over $85 million based on various causes of action, including claims for overpayments, unjust enrichment, fraud, negligent misrepresentation, tortious interference with contract, unfair and deceptive business practices, and civil conspiracy.

6 42 C.F.R. §1001.952(d).

As early as October 2009, LaTonya Mallory, the President & CEO of HDL, sent an email to Dennis Ryan of LeClairRyan, requesting review of a draft P&H agreement prepared by Mallory in which HDL would pay HCPs a P&H fee of $15 per patient. Mallory's email to Ryan specifically stated that the fee is "designed to offset some of the labor cost associated with getting the sample ready for us" and requested that LeClairRyan "review it to make any changes that you think we need to make sure that it is not misconstrued as inducement."

Ryan forwarded Mallory's email to Patrick Hurd of LeClairRyan, stating that he "would like to bounce the inducement question below off [of him]." Internal LeClairRyan documents demonstrate that Hurd expressed concern to Ryan regarding the arrangement, stating ". . . I advise extreme caution in structuring the fee for services arrangement between the lab and physician offices. . . the difference between the $3.00 Medicare rate and the $15 physician fee gives me some concern. . ." We have not identified a response by LeClairRyan to Mallory's email and it is clear that HDL continued to provide P&H payments to HCPs after October 2009.

II. P&H Position Papers

Subsequently, in May 2010, Mallory asked Ryan to review "HDL's Position Statement on Process and Handling Fees paid to Physicians and Partner Laboratories" to determine whether he find's HDL's position "acceptable." Hurd responded to Mallory that he reviewed the paper and provided one "minor revision" to the Conclusion section. The revised Conclusion provided, in part: "The process and handling fee arrangement described above is consistent with the 'arms length, fixed in advance, fair market value' requirements of the applicable Safe Harbor provisions of the federal Anti-kickback Statute and the Stark Law . . ." The Conclusion further referenced the "continued acceptability" of the P&H fee agreements. An analysis from LeClairRyan regarding the applicability of the Stark Law to the P&H payments has not been identified.

Several months later, in February 2011, Mallory sent an email to Hurd (cc Ryan), informing him that a "competitor" reported HDL to the OIG for "inducement" based on HDL's position paper that LeClairRyan previously reviewed. Mallory again requested that LeClairRyan review the document, stating: "You guys have reviewed this document in the past and did not have an issue with it then. However, in light of this new possible interpretation, I'd like you to take a look at it again."

III. Legal Memoranda

LeClairRyan also prepared at least two legal memoranda for HDL regarding the legality of P&H payments. In May 2011, Hurd sent an email to Ryan stating that Mallory requested a "legal opinion letter" that HCP customers can "put in the file." Hurd's email stated that Mallory "essentially dictated" the letter and that "many of her points are valid and supportable", but outlines three concerns in providing the letter. In response, Ryan asked Hurd to "write a vanilla based letter (not a legal opinion) that might work." Hurd agreed to do so, and provided a "vanilla letter" to Ryan the following day. The letter stated, in part, "Neither the purpose nor the intent of this Agreement is to induce any referral of any item or health service to HDL, Inc. . . . It would seem that the Arrangement contemplates an arrangement far different from the provision of in-office phlebotomy services or remuneration to physicians for drawing blood samples. It appears to be an Arms length agreement whose terms are negotiated and fixed in advance based on the fair market value of the services performed by the Provider."

Additionally, in April 2012, Michael Ruggio of LeClairRyan issued to HDL a legal letter regarding P&H payments following the conclusion of a "time and motion study" conducted by a third party vendor. The memorandum concluded that "a fair market value of up to, but not to exceed $36.03 per specimen for processing and handling tasks is appropriate and justifiable. HDL's current agreements with physicians in this regard are well below that amount. Based on this careful study, this arm's-length, fixed-in-advance fair market value fee **will fall into the safe harbor exceptions under Anti-Kickback statutes (and Civil False Claims Act) to alleviate any issue in that regard. . . HDL is acting within applicable statutory laws to pay this fair market fee for processing and handling services**." (emphasis added).

iv. Inquiries and Complaints

Despite numerous concerns raised by HCPs, HDL's competitors, and other third parties regarding the legality of P&H payments, LeClairRyan continued to advise HDL that its P&H payments were indeed legal. For example, in response to an inquiry from a HCP regarding the P&H payment in October 2010, Ryan informed Mallory that HDL is "on solid ground with the OIG advisory opinion . . ."

Subsequently, in December 2010, Mallory forwarded an email to Ryan regarding an analysis of the P&H agreement conducted by a HCP's attorney, which stated, in part:

> . . . assuming that this payment is made when Dr. Reddy orders a lab test on a patient and intends to send the specimen to HDL, the proposed relationship is blatantly illegal. As blatantly illegal as anything that I have seen in a long time. It would be a criminal violation of the federal and state kickback laws, a Stark law problem if Dr. Reddy were to refer Medicare patients, and could form the basis for liability under the false claims act. It is absurd. If Dr. Reddy is only going to function as a draw station for individuals who are not his patients, and he is never going to refer any patients to HDL, then I could rethink it. Otherwise, I STRONGLY recommend that you cease any discussions with HDL and stay as far away from them as you can, no matter what they offer.

In response, Hurd sent a memorandum to Ryan, stating that HDL should not provide P&H payments in Florida due to state law changes. The memorandum stated that HDL ". . . faces significant agency scrutiny, at best, and possible enforcement actions/lawsuits, at worst, under the company's contemplated process and handling fee arrangement." Additionally, with regard to NY, the memorandum recommended "a rigorous and objective study to support the company's determination of the appropriate [P&H] fee."

In March 2011, Mallory sent an email to Hurd and Ryan regarding another inquiry regarding the P&H payments from a HDL competitor, Quest Diagnostics. Mallory's email stated that she received a "very strange email from Quest labs today. Basically, I agree with most of what she has said out of context but when taken in context most is irrelevant." Mallory then asked LeClairRyan whether she needed to call the Quest representative back. Mallory later forwarded to Hurd (cc Ryan) a fax containing FL statute 817.234 and OIG Advisory Opinion 05-08, which Quest sent to Mallory as follow-up to its prior voicemail message.

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Health Regulatory Overview

Agreements between laboratories and HCPs to provide services, free goods, or other items of value were not a new concept in October 2009 when Mallory asked LeClairRyan for legal advice regarding P&H payments. Rather, significant OIG guidance interpreting these arrangements based on the AKS and other health regulatory laws had been issued much earlier, beginning in 1994, and continued to be issued regularly prior to and during the time period in which LeClairRyan provided legal counseling to HDL regarding P&H payments. An overview of the legal and regulatory framework that existed at the time the advice was provided follows.

i. **Law**

The Federal AKS prohibits knowingly and willfully offering, paying, soliciting or receiving any remuneration to refer, purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made, in whole or part, by a Federal health care program, such as Medicare or Medicaid. The remuneration can be in any form (e.g., in cash or in kind), and can be provided directly or indirectly, overtly or covertly. Additionally, the AKS is implicated if any "one purpose" of an arrangement is to induce or reward referrals.

Certain remunerative practices that fit squarely within an AKS exception or safe harbor do not implicate the AKS. For example, the AKS Personal Services Safe Harbor excludes from the definition of "remuneration" a payment provided as compensation for the services of an agent if the following seven requirements are met:

1. The agency agreement is set out in writing and signed by the parties;
2. The agency agreement covers all of the services the agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent;
3. If the agency agreement is intended to provide for the services of the agent on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals;
4. The term of the agreement is for not less than one year;
5. The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs;
6. The services performed under the agreement do not involve the counselling or promotion of a business arrangement or other activity that violates any State or Federal law; and

7. The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.[7]

A relationship that does not fit squarely within an AKS exception or safe harbor is not *per se* illegal. Rather, the government analyzes the "totality of the facts and circumstances" to determine whether the AKS is implicated.

Many states also have similar kickback laws, including some that are more prohibitive than the Federal AKS.

ii. OIG Compliance Program Guidance

The OIG's *Compliance Program Guidance for Clinical Laboratories*, issued in August 1998, was voluntary guidance "intended to assist clinical laboratories in developing effective internal controls that promote adherence to applicable Federal and State law, and the program requirements of Federal, State, and private health plans."[8] Among other things, this OIG Guidance stated that laboratories should develop written policies that "ensure that laboratories are not providing any inducements to gain a physician's business . . ."[9]

iii. OIG Special Fraud Alerts

In 1994, the OIG issued a *Special Fraud Alert: Arrangements for the Provision of Clinical Lab Services*, which stated that because HCPs may refer high volumes of patient specimens daily, "it is essential that the physician's decision regarding where to refer specimens is based only on the best interests of the patient. Whenever a laboratory offers or gives to a source of referrals anything of value not paid for at fair market value, the inference may be made that the thing of value is offered to induce the referral of business."[10] The OIG Special Fraud Alert identified a number of practices that may constitute an inducement in violation of the AKS, including arrangements where a laboratory provides to a HCP free services or services "that are normally the responsibility of the physician's office staff."[11]

In June 2014, the OIG issued a *Special Fraud Alert: Laboratory Payments to Referring Physicians* specifically recognized that blood-specimen collection, processing and packaging arrangements may implicate the AKS "if even one purpose of the payment is to induce or reward referrals of Federal health care program business . . . regardless of whether the payment is fair market value for services rendered."[12]

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7 *Id.*

8 63 Fed. Reg. 45,076, 45,077 (Aug. 24, 1998), available at http://oig.hhs.gov/authorities/docs/cpglab.pdf.

9 *Id.* at 45,081.

10 59 Fed. Reg. 65377 (Dec. 19, 1994), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html.

11 *Id.*

12 OIG, *Special Fraud Alert: Laboratory Payments to Referring Physicians* (June 25, 2014), available at

iv. OIG Advisory Opinions

The OIG has issued a number of Advisory Opinions related to various arrangements between clinical laboratories and HCPs. For example, in OIG Advisory Opinion No. 04-16,[13] the OIG concluded that an arrangement where a laboratory would provide employees and related equipment and supplies at no cost to dialysis facilities for the purpose of preparing specimens for delivery to the laboratory could constitute a violation of the AKS. Specifically, the OIG stated that the free services and supplies for which the dialysis facilities would otherwise be obligated to incur costs constitutes a financial benefit to the facilities. The OIG also stated that these benefits may constitute a "discount", which allows the dialysis facilities to maximize reimbursement from Federal health care programs and for the laboratory to "secure lucrative business in a highly competitive market."

Clearly relevant to the subject matter of this letter is OIG Advisory Opinion No. 05-08,[14] which related to an arrangement in which a laboratory would provide free blood collection supplies and pay the HCPs a fee of $3 - $6 for the collection of blood samples. The OIG determined that this arrangement "would clearly implicate the antikickback statute" because there was a "substantial risk" that the remuneration was provided to HCPs in exchange for referrals to the laboratory. In addition to being "an obvious financial benefit to the referring physician", the OIG stated that the arrangement increased the "risk of overutilization and inappropriate higher costs to the Federal health care programs." The OIG further noted that the arrangement would implicate the Federal FCA and Civil Monetary Penalties Law if the HCP also submitted a claim to Medicare for the blood collection services.

Additional OIG Advisory Opinions in which the OIG concluded that providing services and/or free supplies to HCPs could implicate the AKS include the following:

- OIG Advisory Opinion No. 08-06[15] related to an arrangement in which the laboratory would provide to dialysis facilities free specimen collection containers and test tube labeling services, which typically are conducted by a dialysis facility's employees.

- OIG Advisory Opinion No. 11-17[16] related to an arrangement in which the laboratory would provide to HCPs all necessary services and items for an allergy testing and immunotherapy lab, including personnel, equipment, supplies, training, and billing and collection services. In addition to paying the laboratory a fee equal to sixty percent of the HCP's gross collections from the services, the HCP would provide space to operate the laboratory; administrative staff; general medical office supplies and

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http://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/OIG_SFA_Laboratory_Payments_06252014.pdf.

13 OIG, Advisory Opinion No. 04-16 (Nov. 18, 2004), available at http://oig.hhs.gov/fraud/docs/advisoryopinions/2004/ao0416.pdf.

14 OIG, Advisory Opinion No. 05-08 (June 6, 2005), available at http://oig.hhs.gov/fraud/docs/advisoryopinions/2005/ao0508.pdf.

15 OIG, Advisory Opinion No. 08-06 (May 2, 2008), available at http://oig.hhs.gov/fraud/docs/advisoryopinions/2008/AdvOpn08-06.pdf.

16 OIG, Advisory Opinion No. 11-17 (Nov. 16, 2011), available at http://oig.hhs.gov/fraud/docs/advisoryopinions/2011/AdvOpn11-17.pdf.

furniture; general liability and malpractice insurance; and physician supervision and interpretation of laboratory results.

- OIG Advisory Opinion No. 13-03[17] related to an arrangement in which the laboratory would contract with HCPs to assist in setting up their own clinical laboratory for patients who are not Federal health care program beneficiaries. The OIG noted that specimens for patients who are Federal health care program beneficiaries would be sent to another laboratory, including the laboratory that requested the Advisory Opinion.

- OIG Advisory Opinion No. 14-03[18] related to an arrangement in which a laboratory would pay a nominal per-order fee to an electronic health record ("EHR") services vendor for each laboratory test ordered by a HCP using the EHR system and, in return, the HCP would not incur a transmission fee for such test.

- OIG Advisory Opinion No. 15-04[19] related to an arrangement in which a laboratory would enter into agreements with HCPs to provide all laboratory services for the HCPs' patients and waive all fees for those patients with insurance plans that require them to use a different laboratory.

v. Government Settlements

In November 2010, laboratory Ameritox Inc. reached a civil FCA settlement with the DOJ to resolve allegations that it paid money and provided in-kind services to HCPs to induce referrals for Ameritox's drug-testing services.[20] Ameritox stated that the payments were for administrative work "related to specimen processing for Ameritox's specialized testing", a program that it voluntarily stopped in 2005 prior to the DOJ's investigation.[21] As part of the settlement, Ameritox agreed to pay $16.3 million and entered into a five-year CIA with the OIG.

Analysis

It is clear that LeClairRyan provided negligent legal advice to HDL between at least October 2009 and July 2012. LeClairRyan's counseling to HDL disregarded and misinterpreted Federal and State laws, lacked attention to the regulatory and enforcement environment related to laboratories, and failed to appropriately acknowledge and/or analyze P&H payments based on readily available OIG guidance relevant to laboratories.

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17 OIG, Advisory Opinion No. 13-03 (June 7, 2013), available at http://oig.hhs.gov/fraud/docs/advisoryopinions/2013/AdvOpn13-03.pdf.

18 OIG, Advisory Opinion No. 14-03 (Apr. 1, 2014), available at http://oig.hhs.gov/fraud/docs/advisoryopinions/2014/AdvOpn14-03.pdf.

19 OIG, Advisory Opinion No. 15-04 (Mar. 18, 2015), available at http://oig.hhs.gov/fraud/docs/advisoryopinions/2015/AdvOpn15-04.pdf.

20 *United States ex rel. Maul et al. v. Ameritox LLC et al.*, No. 8:07-cv-00953 (M.D. Fla.).

21 See, http://www.tampabay.com/news/business/corporate/drug-testing-company-to-pay-163-million-to-settle-kickback-claims/1134676; http://articles.baltimoresun.com/2013-09-03/business/bs-bz-ameritox-lawsuits-20130830_1_millennium-pain-management-baltimore-school.

If LeClairRyan attorneys reviewed and applied the OIG's analysis in OIG Advisory Opinion No. 05-08,[22] they should have reached the conclusion that HDL's P&H payments violated the Federal AKS. In its analysis of the proposed arrangement, the OIG stated that "payments for blood drawing services that may exceed what the Lab receives for such services and supplies from Medicare would clearly implicate the anti-kickback statute." HDL paid HCPs up to $20 per sample, far exceeding the $3-$6 fee in the proposed arrangement and $3 fee paid by Medicare. Additionally, the rationale provided by the OIG to support its conclusion applied equally to the HDL P&H payments:

- There was a "substantial risk" that the laboratory's intent for the remuneration was to induce referrals to the laboratory from HCPs;
- Compensation that exceeded the Medicare reimbursement rate provided an "obvious financial benefit to the referring physician", again suggesting that the remuneration is to induce referrals; and
- The remuneration provided a "strong incentive to order more blood tests", resulting in overutilization of the laboratory's services and inappropriate higher costs to Federal health care programs.

LeClairRyan also had numerous opportunities to counsel HDL that P&H payments were illegal and failed to do so. During the relevant time period, Mallory asked LeClairRyan to review agreements and position papers, to draft memoranda, and to "take a look" at documents previously reviewed and approved by LeClairRyan in light of industry developments. Further, HDL sent multiple inquiries from customers, HDL competitors and other third parties to LeClairRyan for review, including an email from a HCP's attorney that clearly stated that the P&H payments were "blatantly illegal. As blatantly illegal as anything that I have seen in a long time."

As a direct result of LeClairRyan's negligence, HDL suffered significant harm, financial and otherwise. The estate is conducting an investigation of HDL and various third parties, including LeClairRyan, pursuant to Bankruptcy Rule 2004 and Section 105(a) of the Bankruptcy Code ("Rule 2004 Investigation"). This demand is without prejudice to any and all claims and causes of action discovered during the Rule 2004 Investigation including, but not limited to, LeClairRyan's legal counseling to HDL regarding the BlueWave agreement and HDL's billing practices. Additionally, the applicable statute of limitations, which was tolled until April 25, 2016 pursuant to the Agreement to Toll Lawsuit Limitations Periods effective April 23, 2015 between HDL and LeClairRyan, may be further extended pursuant to Sections 108 and 546 of the Bankruptcy Code.

Damages

HDL has incurred no less than $250 million in damages as a result of the DOJ investigation, DOJ Settlement, Civil Litigation, and bankruptcy costs and restructuring. HDL believes that LeClairRyan bears responsibility for a significant portion of the damages to HDL.

HDL is willing to compromise this claim in order to avoid litigation. Please advise us within seven (7) business days whether you are interested in pursuing settlement negotiations. I am available

22 *Supra*, note 14.

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to meet with you on Wednesday, November 4, in the afternoon in Richmond or Thursday, November 5, in NYC to further discuss settlement negotiations; I will be accompanied by counsel and the meeting will be subject to FRCP 408. If settlement negotiations are not pursued, I will instruct counsel to the estate to file a complaint related to this matter.

Please let me know if I can provide any further information that would facilitate a prompt resolution.

Sincerely,

Health Diagnostics Laboratory, Inc.

By: Richard Arrowsmith
Chief Restructuring Officer
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rarrowsmith@alvarezandmarsal.com

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ATTACHMENT A
TIMELINE OF SELECT KEY FACTS RELATED TO P&H PAYMENTS

DATE	SUMMARY OF KEY INFORMATION
10/26/09	T. Mallory (HDL) requests via email that D. Ryan (LCR) review a draft P&H agreement prepared by Mallory in which HDL would pay HCPs a P&H fee of $15/patient. Mallory informs Ryan that this cost is "designed to offset some of the labor cost associated with getting the sample ready for us." Mallory asks Ryan to "review it to make any changes that you think we need to make sure that it is not misconstrued as inducement." Ryan forwards the email to P. Hurd (LCR), stating "would like to bounce the inducement question below off you."
10/27/09	Email from Hurd to Ryan re: draft P&H agreement from HDL. Hurd states: "my recollection is that such a fee for prep services and applied at the same amount to Fed and non-Fed beneficiaries does not run afoul of the Anti-kickback." Hurd further states that he wants to confirm that "no recent OIG opinions have slipped past me and may have a suggested revision to the attachment."
10/28/09	Email from Hurd to Ryan: "... I advise extreme caution in structuring the fee for services arrangement between the lab and physician offices... the difference between the $3.00 Medicare rate and the $15 physician fee gives me some concern..." Hurd further states in the email that he just attended the DC Health Law Summit and spoke with OIG attorneys about the issue.
12/9/09	Email from Mallory to Ryan asking him to prepare an agreement with BlueWave based on the attached terms. The term sheet includes, in relevant part: "7. P&H fees will be paid to physicians. Target amount is $15-$21/patient. This cost will be paid by HDL based on time motion studies."
5/19/10 (follow-up email sent 7/14/10)	Email from Mallory to Ryan asking him to "review the attached document to see if you find our position acceptable..." The attached document, dated May 1, 2010, is titled, "HDL's Position Statement on Process and Handling Fees paid to Physicians and Partner Laboratories."
7/6/10	Email from Mallory to Ryan, requesting review of HDL Laboratory Processing Services Agreement
7/26/10	Email from Hurd to Mallory, stating that he reviewed the paper and provided one "minor revision" to the Conclusion section. Track changes

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DATE	SUMMARY OF KEY INFORMATION
	in the document indicate that LCR changed the language as follows: "The process and handling fee arrangement described above is consistent with the 'arms length, fixed in advance, fair market value' requirements of the applicable Safe Harbor provisions of the federal Anti-kickback Statute and the Stark Law. HDL will consistently evaluate this position and consult with external legal counsel as to its continued acceptability and we recommend all clients do the same." Mallory forwards the paper to C. Dent (Bluewave) and B. Johnson, stating that "the attorneys reviewed and approved our p&h position. . ."
8/3/10	Email from Ryan to Mallory, providing revisions to letter from HDL to participating physicians regarding the billing process for P&H payments.
10/25/10	Legal inquiry from tnmed.org re: P&H fee stating, in part: "It was in regards to one of your sales professionals contacting a physician and telling him that for every specimen he sends to your lab you will pay him $20. My question, how is this not a kickback and a violation of federal law?" In email discussion with Mallory regarding inquiry follow-up, Ryan states: "We are on solid ground with the OIG advisory opinion . . ."
11/5/10	Mallory forwards to Ryan an email from an HDL client that requests "the opinion/legal letters regarding anti 'kick back' to practices and how HDL validated the P&H fee for AAPI." Mallory states, "They just want to hear from our attorney that we are in a solid position with our P&H and it is a big possible acct." Ryan responds, "Will do."
12/13/10	Mallory forwards an email to Ryan regarding the P&H agreement that HDL sent to Dr. Reddy's medical practice. Dr. Reddy provides, in response, the analysis from his own attorney (Lester Perling), which states, in part: ". . . assuming that this payment is made when Dr. Reddy orders a lab test on a patient and intends to send the specimen to HDL, the proposed relationship is blatantly illegal. As blatantly illegal as anything that I have seen in a long time. It would be a criminal violation of the federal and state kickback laws, a Stark law problem if Dr. Reddy were to refer Medicare patients, and could form the basis for liability under the false claims act. It is absurd. If Dr. Reddy is only going to function as a draw station for individuals who are not his patients, and he is never going to refer any patients to HDL, then I could rethink it. Otherwise, I STRONGLY recommend that you cease any discussions with HDL and stay as far away from them as you can, no matter what they offer."

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DATE	SUMMARY OF KEY INFORMATION
12/16/10	Mallory sends email to Bluewave regarding "an update on the discussions that our attorney had . . . with Dr. Reddy's attorney, Lester Perling. . .", including that Mr. Perling informed them that a new law in FL will make this arrangement illegal.
1/28/11	Memorandum from Hurd to Ryan re: HDL in Florida, New York. Concludes that, with regard to FL, HDL ". . . faces significant agency scrutiny, at best, and possible enforcement actions/lawsuits, at worst, under the company's contemplated process and handling fee arrangement." Also concludes, with regard to NY, that it is critical for HDL to "conduct a rigorous and objective study to support the company's determination of the appropriate fee for its services agreement with health care providers."
2/15/11	Email from Mallory to Hurd (cc Ryan), informing him that a "competitor" reported HDL to the OIG for "inducement" based on the last sentence of paragraph #1 of HDL's position paper. "You guys have reviewed this document in the past and did not have an issue with it then. However, in light of this new possible interpretation, I'd like you to take a look at it again."
3/30/11	Mallory email to Hurd and Ryan, stating that she received a "very strange email from Quest labs today. Basically, I agree with most of what she has said out of context but when taken in context most is irrelevant. I don't see why I need to call her back . . . do you???"
4/13/11	Fax from J. Hutchison, Compliance Director, Sales and Marketing, Quest Diagnostics to Mallory, providing documents referenced in her voicemail. Attachments are FL statute 817.234 and OIG Advisory Opinion 05-08.
4/18/11	Mallory sends fax from Quest to Hurd (cc Ryan), asking him to follow-up with Quest.
5/3/11	Email from Hurd to Ryan stating that Mallory has requested a "legal opinion letter" that HCP customers can "put in the file." Hurd states that Mallory "essentially dictated" the letter and that "many of her points are valid and supportable." After outlining three concerns related to providing the letter, Hurd concludes the email by stating: "Whatever financial gains Tonya and her Florida marketing reps perceive that merits providing a legal opinion letter to this inquiring practice I believe is outweighed by the risks created by doing so. At some point, a subtle and nuanced legal posture morphs into blatant efforts to induce referrals. Let's not get there..."

HealthDiagnosticLaboratoryInc.
beyond disease diagnosis

DATE	SUMMARY OF KEY INFORMATION
5/4/11	Ryan asks Hurd to "write a vanilla based letter (not a legal opinion) that might work." Hurd agrees to do so.
5/5/11	Hurd provides a "vanilla letter" to Ryan. The letter states, "Neither the purpose nor the intent of this Agreement is to induce any referral of any item or health service to HDL, Inc. . . . It would seem that the Arrangement contemplates an arrangement far different from the provision of in-office phlebotomy services or remuneration to physicians for drawing blood samples. It appears to be an Arms length agreement whose terms are negotiated and fixed in advance based on the fair market value of the services performed by the Provider."
9/21/11	Letter from Exponent to M. Ruggio (LCR) providing requested CV and Exponent overview materials.
10/5/11	Ruggio sends email to Mallory stating, "per your request we have checked Florida law and the status has not changed since the Pat Hurd memo of January 28, 2011."
10/21/11	Ruggio sends Exponent proposal to Mallory, stating "I have been working with our time and motion study consultants . . ."
4/19/12	D. Ryan (now HDL Exec VP) sends email to C. Sims (LCR) re: Exponent analysis, stating ". . . you may have mentioned the P&H to Larry, but if not, important that he is aware of what the industry is doing as he understands all of the compliance issues. I have pushed for this time and motion study that Mike Ruggio has been spearheading. . ."
4/20/12	Final Exponent report re: time and motion study provided to HDL.
4/20/12	In response to email from Sims to L. Freedman (Patton Boggs) providing final Exponent report re: P&H fees, Freedman responds that "Lab payment to referral sources for administrative services related to specimen collection is under high scrutiny" and provides the Ameritox DOJ settlement. Freedman also sends OIG Advisory Opinion 05-08 on blood draws to Sims under separate cover. Sims forwards emails from Freedman to Ryan.
4/25/12	Ruggio sends legal analysis letter to Ryan. Ryan responds that it should be addressed to Mallory and ". . . it would be good if you could go into some more detail on what HDL currently pays for p&h and how this study can support this referencing the need to avoid any regulatory issues. . ."
4/27/12	Ruggio provides Time and Motion Study legal letter to Mallory. Letter concludes that "a fair market value of up to, but not to exceed $36.03 per

DATE	SUMMARY OF KEY INFORMATION
	specimen for processing and handling tasks is appropriate and justifiable. HDL's current agreements with physicians in this regard are well below that amount. Based on this careful study, this arm's-length, fixed-in-advance fair market value fee will fall into the safe harbor exceptions under Anti-Kickback statutes (and Civil False Claims Act) to alleviate any issue in that regard... HDL is acting within applicable statutory laws to pay this fair market fee for processing and handling services."
7/13/12	Mallory sends "Compliance Summary" to Ryan and D. Kung (HDL GC). Ryan sends same to Sims, requesting that he review it before a discussion with Ryan and Kung. Compliance Summary includes, among other things, "P&H for doctor office", "P&H for lab partner/draw site", "Time & Motion Study", and "P&H Position Statement."

Brown, Tyler

From:	Brown, Tyler
Sent:	Monday, November 02, 2015 6:21 PM
To:	Joseph McConnell (joemcconnell50@gmail.com); William Broscious; Kim Taylor (KTaylor@kbbplc.com)
Cc:	Harbour, Jason
Subject:	October 27 HDL Board Minutes.DOCX
Attachments:	October 27 HDL Board Minutes_57950167_2-c.DOCX

Attached is a draft of the minutes of the HDL Board meeting held Oct. 27, 2015.

I presume we are still on for a Board meeting on Wednesday, Nov. 4, at 3 p.m. Rick Arrowsmith previously circulated dial-in instructions for that call, but it looks like he only sent those instructions to the Board members themselves and not to counsel. Please let me know if you do not have them.

Do you plan to circulate a Board agenda tomorrow? In addition to approving the minutes, we probably should discuss the G3 sale process, the Bar Date Order, the D&O coverage issues, and the status of the plan and disclosure statement. Please let me know in the event you would like us to be prepared to address any other issues.

In addition to having Rick Arrowsmith and Doug Sbertoli on the call, I would like to have Jay Moore join the call and have Lon Berk, our insurance expert, available in case the Board wants to ask him any questions.

Thanks.

-Tyler

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PRIVILEGED AND CONFIDENTIAL

Board of Directors Meeting Minutes

Date: October 27, 2015

Attendees: Joe McConnell, Russ Warnick, Bob Galen, Noel Bartlett, John Young

Minutes: Joe McConnell

Participants: Hunton & Williams, LLP ("H&W"), counsel to the Company; Alverez & Marsal Holdings LLC, CRO and Financial Advisor to the Company; Doug Sbertoli, independent contractor to the Company; McGuireWoods LLP, counsel to Russ Warnick; Barnes & Thornburg LLP, counsel to Noel Bartlett and Bob Galen; Kepley Broscious & Biggs, PLC, counsel to Joe McConnell

Call to order – The meeting commenced at approximately 2:00 p.m.

Minutes of Prior Meetings

Minutes of the Board meeting held on October 13, 2015 were approved by unanimous vote, with one modification. The minutes shall reflect that Bob Galen also was represented at the meeting by Barnes & Thornburg LLP.

Report on Hearing of October 22

Counsel to the Company provided a report on the results of the hearing held on October 22, 2015, including on the motion of the Creditors' Committee for examination of certain parties under Rule 2004, the motion of the Company to extend the exclusivity periods by 90 days, and the motion of the Company to substitute Rick Arrowsmith for Martin McGahan as the CRO of the Company.

Bar Date Order

Counsel for the Company described the situation concerning the Bar Date Order and whether to include in the Bar Date Order a carve-out in favor of the directors and officers from the obligation to file indemnity, contribution and reimbursement claims by the Bar Date provided in the proposed order. The Board voted unanimously that the Company should seek a carve-out from the Bar Date Order for indemnification, contribution and reimbursement claims in order to best preserve the proceeds of the D&O policy from any defense to liability of the carriers. The Board requested that the Company's counsel work with counsel to individual Board members to attempt to reach a resolution with counsel to the Creditors' Committee on the carve-out issue.

Weekly Board Meetings

Following the report of Company counsel on the status of the bankruptcy cases, the Board decided unanimously that is should schedule weekly meetings of the Board, unless and until it is determined that less or more frequent meetings would be appropriate. The targeted day and time for such weekly meetings shall be Wednesdays at 3 p.m., unless otherwise scheduled.

Chapter 7 versus Chapter 11 Analysis

The Company's counsel and CRO next presented an overview of the benefits and detriments of converting the cases to chapter 7 versus attempting to confirm a chapter 11 liquidating plan. The Board asked numerous questions regarding the overview but did not call a vote on the appropriate exit strategy.

Update on Biotech 8

The CRO provided an update on discussions with the Lingerfelts and another investor in Biotech 8 on the status of the sale of the property and other discussions on matters relevant to any sale of the headquarters building.

Litigation

Counsel to the Company provided an overview of discussions with Ropes & Gray regarding the desirability and strategy involved in re-initiating litigation with Cigna regarding the health care payments Cigna owes the company.

In addition, the CRO reported that a demand letter had been sent to a law firm regarding advice provided to the company on its prior business practices and that a meeting with the law firm had been requested. At the request of the Board, counsel agreed to provide the Board with a copy of the demand letter.

Plan Overview

Counsel to the Company provided the Board with a brief overview of the strategy contemplated for the chapter 11 plan of liquidation. Counsel confirmed their prior commitment to provide a draft of the plan to the Board prior to presentation to the Committee. A draft of the plan is expected to be circulated to the Board the week of November 2, 2015.

D&O Policies

The CRO reported on the efforts to secure extending reporting period coverage and the efforts to secure a new policy covering the post-petition period. The Board unanimously approved of moving forward with securing the new ACE D&O policy for the post-petition period unless counsel to the Creditors' Committee objected. No opposition was anticipated.

The Board discussed the need to put the D&O carriers on notice of any and all claims or circumstances that might give rise to a claim under the D&O policies. While notice has been provided to the carriers, the Board determined that additional notice would be prudent.

True Health Sale Schedules

At the request of the Board, counsel to the Company committed to provide copies of the schedules from the True Health sale agreement to the Board; provided, however, that with respect to Schedule 3.1, counsel would seek a waiver of the protective order from True Health, if required, in order to share Schedule 3.1 with the Board.

Adjourn

The meeting was adjourned at approximately 5:05 p.m.